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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,890	01/13/2004	H. Phillip Koeffler	066783-0144	3623
41552            7590            02/27/2007 MCDERMOTT, WILL & EMERY 4370 LA JOLLA VILLAGE DRIVE, SUITE 700 SAN DIEGO, CA 92122			EXAMINER HUGHES, ALICIA R	
			ART UNIT 1614	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS	02/27/2007	PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/756,890	KOEFFLER ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Alicia R. Hughes	1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 22 August 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 61-115 is/are pending in the application.
- 4a) Of the above claim(s) 61-66, 68, 71-73, 75, 77, 79, 82, 84, 86, 88-94, 98-100, 102, 104, 106, 109, 111, 113, and 115 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 67,69,70,74,76,78,80,81,83,85,87,95-97,101,103,105,107,108,110,112 and 114 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 13 January 2004 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date: _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ( <u>6 sheets</u> )  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Claims***

Claims 67, 69, 70, 74, 76, 78, 80, 81, 83, 85, 87, 95-97, 101, 103, 105, 107-108, 110, 112, and 114 are pending and the subject of this Office Action. Claims 61-66, 68, 71-73, 75, 77, 79, 82, 84, 86, 88-94, 98-100, 102, 104, 106, 109, 111, 113, and 115 are withdrawn from consideration, being drawn to a non-elected invention. See 37 C.F.R. 1.142(b). Applicant cancelled claims 1-60 in the response filed on 07 April 2006.

### ***Restriction Requirement***

The Office acknowledges receipt of Applicants' response to the Requirement for Restriction and notes that the elections in the Applicants' response, is with traverse.

While Applicant acknowledges that the inventions of Groups I and II are patentably distinct, Applicant nevertheless argues that a search for one will inevitably encompass a search for the other.

In consideration of Applicants' acknowledgement that the groups support different inventions, and furthermore, since the methodologies and agent applications to the same are different, the restriction requirement, upon reconsideration, is deemed proper and hereby made FINAL.

### ***Claim Rejections - 35 U.S.C. §112.2***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 69, 78, 96, and 105 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 69, 78, 96, and 105, as written, are vague and indefinite, because claim includes reference to "PS341," but does not disclose to what PS341 refers. When Applicant makes a claim which references a particular for the first time in a claim set, Applicant should write out the full name of the particular to which he refers and accompany that full name with the abbreviation in brackets, if desirous of using an abbreviation of same thereafter.

***Claim Rejections – 35 U.S.C. §103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 67, 69, 83, 85, 95-96, 110, and 112, are rejected under 35 U.S.C. 103(a) as being obvious over WO 02/30430 A1 [hereinafter referred to as "Blanchard, et al"] in view of U.S. Patent No. 6624138 [hereinafter referred to as "Sung, et al"] and in further view of ElGenidi, M., *Prevention of Chemotherapy-Induced Alopecia by the New Digital Scalp Cooler Device* (Abstract), European Journal of Cancer, vol. 37, supplement 6, April 2001, page S357 (abstract page 1)[hereinafter referred to as "ElGenidi"]

Blanchard et al. teach a method of preventing or treating chemotherapy-induced alopecia in a mammal by administering an effective amount of paricalcitol with at least one chemotherapeutic agent, for example 5-fluorouracil or adriamycin, that induces alopecia (Page 7, lines 17-26 and page 19, lines 1-22, claims 1-5).

ElGenidi teach that chemotherapeutic agents are known to induce alopecia. (Abstract page 1). Sung et al. teach that paracalcitol may be used for treating targeted tissues that contain cancer or cancerous tumors. (Col. 17, lines 51-57 and 62-63, Col. 13, lines 7-16, Col. 8, lines 49-61, and Col. 9, lines 1-5).

One of ordinary skill in the art would be motivated to combine the teachings of Blanchard et al with the teachings of ElGenidi and Sung, et al., because the references teach overlapping subject matter, most notably, the treatment of cancer and cancer treatment-related conditions.

In light of the foregoing, one of ordinary skill in the art would be motivated to apply the teachings of Blanchard et al., Sung et al, and ElGenidi to the present invention, because anti-cancer/chemotherapeutic agents are known to reduce the severity of proliferative disorders associated with cancer, and paricalcitol is a known treatment for tissues that contain cancerous

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cells and/or tumors. When used together, it would be obvious to one of ordinary skill in the art that the proliferation of cancers and their associated tumors, would be diminished.

Absent any evidence to the contrary, in light of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art to combine paricalcitol with 5-fluorouracil and to combine paricalcitol with adriamycin to reduce the severity of proliferative disorders.

Claims 67, 69, 70, 76, 80, 81, 87, 95-97, 103, 107-108, and 114 are rejected under 35 U.S.C. 103(a) as being obvious over W/O 00/30430 A1 [hereinafter referred to as "Blanchard, et al"] in view of U.S. Patent No. 7001888 [hereinafter referred to as "Tidmarsh et al."], in further view of U.S. Patent No. 6624138 [hereinafter referred to as "Sung, et al"] and in further view of ElGenidi, M., *Prevention of Chemotherapy-Induced Alopecia by the New Digital Scalp Cooler Device* (Abstract), European Journal of Cancer, vol. 37, supplement 6, April 2001, page S357 (abstract page 1)[hereinafter referred to as "ElGenidi"].

The teachings of Blanchard, et al, Sung et al., and ElGenidi, as discussed herein, *supra*, are incorporated into this rejection by reference. The references noted do not teach daunomycin, arsenic trioxide, taxol, and methotrexate are chemotherapeutic agents, however, Tidmarsh et al. do (Col. 17, lines 43-46, Col. 18, lines 12, 19-25).

One of ordinary skill in the art would be motivated to combine the teachings of Blanchard et al with the teachings of ElGenidi, Sung, et al., and Tidmarsh, et al., because the references teach overlapping subject matter, most notably, the treatment of cancer and cancer treatment-related conditions.

In light of the foregoing, one of ordinary skill in the art would be motivated to apply the teachings of Blanchard et al., Sung et al, ElGenidi, and Tidmarsh, et al., to the present invention,

because anti-cancer/chemotherapeutic agents are known to reduce the severity of proliferative disorders associated with cancer, and paricalcitol is a known treatment for tissues that contain cancerous cells and/or tumors. When used together, it would be obvious to one of ordinary skill in the art that the proliferation of cancers and their associated tumors, would be diminished.

Absent any evidence to the contrary, in light of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art to combine paricalcitol with daunomycin, to combine paricalcitol with arsenic trioxide, to combine paricalcitol with taxol, and to combine paricalcitol with methotrexate to reduce the severity of proliferative disorders.

Claims 67, 69, 74, 78, 95-96, 101, and 105 are rejected under 35 U.S.C. 103(a) as being obvious over W/O 00/30430 A1 [hereinafter referred to as "Blanchard, et al"] in view of U.S. Patent No., 5795909 [hereinafter referred to as Shashoua et al."], in further view of U.S. Patent No. 6624138 [hereinafter referred to as "Sung, et al"] and in further view of ElGenidi, M., *Prevention of Chemotherapy-Induced Alopecia by the New Digital Scalp Cooler Device* (Abstract), European Journal of Cancer, vol. 37, supplement 6, April 2001, page S357 (abstract page 1)[hereinafter referred to as "ElGenidi"].

The teachings of Blanchard, et al, Sung et al., and ElGenidi, as discussed herein, *supra*, are incorporated into this rejection by reference. The references noted do not teach that dexamethasone and PS341 are chemotherapeutic agents, however, Shashoua et al. do (Col. 1, lines 8-18, and Col. 5 lines 20-21, Col. 20, lines 63-64, and Col. 32, lines 65).

One of ordinary skill in the art would be motivated to combine the teachings of Blanchard et al with the teachings of ElGenidi, Sung, et al., and Shashoua, et al., because the

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references teach overlapping subject matter, most notably, the treatment of cancer and cancer treatment-related conditions.

In light of the foregoing, one of ordinary skill in the art would be motivated to apply the teachings of Blanchard et al., Sung et al, ElGenidi, and Tidmarsh, et al., to the present invention, because anti-cancer/chemotherapeutic agents are known to reduce the severity of proliferative disorders associated with cancer, and paricalcitol is a known treatment for tissues that contain cancerous cells and/or tumors. When used together, it would be obvious to one of ordinary skill in the art that the proliferation of cancers and their associated tumors, would be diminished.

Absent any evidence to the contrary, in light of the foregoing, it would have been *prima facie* obvious to one of ordinary skill in the art to combine paricalcitol with PS341 and to combine paricalcitol with dexamethasone to reduce the severity of proliferative disorders.

### **Conclusion**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see <http://pair-direct-uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

29 January 2007

ARH

*Ardin H Marschel 2/20/07*  
ARDIN H. MARSCHEL  
SUPERVISORY PATENT EXAMINER